

General

Guideline Title

Clinical policy: emergency department management of patients needing reperfusion therapy for acute ST-segment elevation myocardial infarction.

Bibliographic Source(s)

Promes SB, Glauser JM, Smith MD, Torbati SS, Brown MD, American College of Emergency Physicians. Clinical policy: emergency department management of patients needing reperfusion therapy for acute ST-segment elevation myocardial infarction. Ann Emerg Med. 2017 Nov;70(5):724-39. [28 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Fesmire FM, Brady WJ, Hahn S, Decker WW, Diercks DB, Ghaemmaghami CA, Nazarian D, Jagoda AS, American College of Emergency Physicians Clinical Policies Subcommittee. Clinical policy: indications for reperfusion therapy in emergency department patients with suspected acute myocardial infarction. Ann Emerg Med. 2006 Oct;48(4):358-83. [86 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

| Assessment | Standard of Trustworthiness |
|------------|--|
| YES | Disclosure of Guideline Funding Source |
| | Disclosure and Management of Financial Conflict of Interests |

| | Guideline Development Group Composition |
|---------|---|
| UNKNOWN | Multidisciplinary Group |
| YES | Methodologist Involvement |
| | Patient and Public Perspectives |
| | Use of a Systematic Review of Evidence |
| | Search Strategy |
| | Study Selection |
| | Synthesis of Evidence |
| | Evidence Foundations for and Rating Strength of Recommendations |
| | Grading the Quality or Strength of Evidence |
| | Benefits and Harms of Recommendations |
| | Evidence Summary Supporting Recommendations |
| | Rating the Strength of Recommendations |
| 11111 | Specific and Unambiguous Articulation of Recommendations |
| 11111 | External Review |
| | Updating |

Recommendations

Major Recommendations

Definitions for the class of evidence (Class I-III) and level of recommendations (A-C) are provided at the end of the "Major Recommendations" field.

In adult patients having an ST-segment elevation myocardial infarction (STEMI), are there patients for whom treatment with fibrinolytic therapy decreases the incidence of major adverse cardiac events (MACE) when percutaneous coronary intervention (PCI) is delayed?

Level A recommendations. None specified.

Level B recommendations. Fibrinolytics may be administered to patients when door-to-balloon (D2B) time is anticipated to exceed 120 minutes.

Level C recommendations. A dose reduction should be considered when administering fibrinolytics to patients aged 75 years or older.

In adult patients having a STEMI, does transfer to a PCI center decrease the incidence of MACE? Level A recommendations. None specified. Level B recommendations. To decrease the incidence of MACE, patients with STEMI should be transferred to a PCI-capable hospital as soon as possible.

Level C recommendations. None specified.

In adult patients undergoing reperfusion therapy, should opioids be avoided to prevent adverse outcomes?

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. Because safety has not been established, clinical judgment should be used in deciding whether to provide or withhold morphine in patients undergoing reperfusion therapy.

Definitions

Class of Evidence

Literature Classification Schema*

| Design/Class | Therapy† | Diagnosis‡ | Prognosis§ |
|--------------|---|---|---|
| 1 | Randomized controlled trial or meta-analysis of randomized trials | Prospective cohort using a criterion standard or meta-analysis of prospective studies | Population prospective cohort or meta-analysis of prospective studies |
| 2 | Nonrandomized trial | Retrospective observational | Retrospective cohort Case control |
| 3 | Case series | Case series | Case series |

^{*}Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

Approach to Downgrading Strength of Evidence*

| Downgrading | Design/Class | | | |
|----------------|--------------|-----|-----|--|
| | 1 | 2 | 3 | |
| None | I | II | III | |
| 1 level | II | III | X | |
| 2 levels | III | X | X | |
| Fatally flawed | X | X | X | |

^{*}See the "Description of Methods Used to Analyze the Evidence" field for more information.

Translation of Class of Evidence to Recommendation Levels

Based on the strength of evidence grading for each critical question (see the Evidentiary Table in the original guideline document), the subcommittee drafted the recommendations and the supporting text synthesizing the evidence using the following guidelines:

Level A recommendations. Generally accepted principles for patient care that reï¬,ect a high degree of clinical certainty (e.g., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reï¬,ect moderate clinical certainty (e.g., based on evidence from 1 or more Class

[†]Objective is to measure therapeutic efficacy comparing interventions.

[‡]Objective is to determine the sensitivity and specificity of diagnostic tests.

 $[\]S{Objective}$ is to predict outcome, including mortality and morbidity.

of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances in which consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and publication bias, among others, might lead to such a downgrading of recommendations.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Acute ST-segment elevation myocardial infarction (STEMI)

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Cardiology

Emergency Medicine

Intended Users

Health Care Providers

Physicians

Guideline Objective(s)

- To address key issues in reperfusion for patients with acute ST-segment elevation myocardial infarction (STEMI)
- To derive evidence-based recommendations to answer the following clinical questions:
 - In adult patients having a STEMI, are there patients for whom treatment with fibrinolytic therapy decreases the incidence of major adverse cardiac events (MACE) when percutaneous coronary intervention (PCI) is delayed?

- In adult patients having a STEMI, does transfer to a PCI center decrease the incidence of MACE?
- In adult patients undergoing reperfusion therapy, should opioids be avoided to prevent adverse outcomes?

Target Population

Adult patients presenting to the emergency department (ED) with suspected acute ST-segment elevation myocardial infarction (STEMI)

Note: This guideline is not intended for pediatric patients, pregnant patients, or patients with contraindications to fibrinolytic treatment.

Interventions and Practices Considered

- 1. Administration of fibrinolytics when door-to-balloon (D2B) time is anticipated to exceed 120 minutes
- 2. Consideration of reduced dosage when administering fibrinolytics to patients aged 75 years and older
- 3. Transfer to a percutaneous coronary intervention (PCI)-capable hospital
- 4. Use of clinical judgment when deciding to provide or withhold morphine in patients undergoing reperfusion therapy

Major Outcomes Considered

- Incidence of major adverse cardiac events (MACE)
- Mortality
- Myocardial infarction (MI), stroke, and revascularization
- · Adverse effects of opioids

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This clinical policy is based on a systematic review with critical analysis of the medical literature meeting the inclusion criteria. Searches of MEDLINE, MEDLINE InProcess, Cochrane, EMBASE, and Scopus databases were performed. All searches were limited to human studies published in English. Specific key words/phrases, years used in the searches, dates of searches, and study selection are identified under each critical question in the original guideline document. In addition, relevant articles from the bibliographies of included studies and more recent articles identified by committee members and reviewers were included.

Number of Source Documents

Study Selection

Critical Question 1

Two hundred thirty-four articles were identified in the search. Forty-three articles were selected from the search results for further review, with 6 Class III studies included for this critical question.

Critical Question 2

Two hundred two articles were identified in the search. Forty-five articles were selected from the search results for further review, with 1 Class II and 1 Class III study included for this critical question.

Critical Question 3

Twenty-five articles were identified in the search. Nine articles were selected from the search results for further review, with 1 Class III study included for this critical question.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence

Literature Classification Schema*

| Design/Class | Therapy† | Diagnosis‡ | Prognosis§ |
|--------------|---|---|---|
| 1 | Randomized controlled trial or meta-analysis of randomized trials | Prospective cohort using a criterion standard or meta-analysis of prospective studies | Population prospective cohort or meta-analysis of prospective studies |
| 2 | Nonrandomized trial | Retrospective observational | Retrospective cohort Case control |
| 3 | Case series | Case series | Case series |

^{*}Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

Approach to Downgrading Strength of Evidence*

| Downgrading | Design/Class | | | |
|----------------|--------------|-----|-----|--|
| | 1 | 2 | 3 | |
| None | I | II | III | |
| 1 level | II | III | X | |
| 2 levels | III | X | X | |
| Fatally flawed | X | X | X | |

^{*}See the "Description of Methods Used to Analyze the Evidence" field for more information.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

[†]Objective is to measure therapeutic efficacy comparing interventions.

[‡]Objective is to determine the sensitivity and specificity of diagnostic tests.

 $[\]S{\mbox{Objective}}$ is to predict outcome, including mortality and morbidity.

Description of the Methods Used to Analyze the Evidence

Assessment of Classes of Evidence

Two methodologists independently graded and assigned a preliminary Class of Evidence for all articles used in the formulation of this clinical policy. Class of Evidence is delineated whereby an article with design 1 represents the strongest study design and subsequent design classes (i.e., design 2 and design 3) represent respectively weaker study designs for therapeutic, diagnostic, or prognostic studies, or metaanalyses (see the "Rating Scheme for the Strength of the Evidence" field). Articles are then graded on dimensions related to the study's methodological features, such as randomization processes, blinding, allocation concealment, methods of data collection, outcome measures and their assessment, selection and misclassification biases, sample size, generalizability, data management, analyses, congruence of results and conclusions, and conflicts of interest. Using a predetermined process combining the study's design, methodological quality, and applicability to the critical question, articles received a Class of Evidence grade. An adjudication process involving discussion with the original methodologist graders and at least one additional methodologist was then used to address any discordance in original grading, resulting in a final Class of Evidence assignment (i.e., Class I, Class II, Class III, or Class X) (see the "Rating Scheme for the Strength of the Evidence" field). Articles identified with fatal flaws or ultimately determined to not be applicable to the critical question received a Class of Evidence grade "X" and were not used in formulating recommendations for this policy. However, content in these articles may have been used to formulate the background and to inform expert consensus in the absence of robust evidence. Grading was done with respect to the specific critical questions; thus, the Class of Evidence for any one study may vary according to the question for which it is being considered. As such, it was possible for a single article to receive a different Class of Evidence rating when addressing a different critical question. Question-specific Classes of Evidence grading may be found in the Evidentiary Table in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process, including internal and external review, and is based on the existing literature; when literature was not available, consensus of Clinical Policies Committee members was used and noted as such in the recommendation (i.e., consensus recommendation).

When possible, clinically oriented statistics (e.g., likelihood ratios, number needed to treat) are presented to help the reader better understand how the results may be applied to the individual patient. For a definition of these statistical concepts, see Appendix C in the original guideline document.

Rating Scheme for the Strength of the Recommendations

Translation of Class of Evidence to Recommendation Levels

Based on the strength of evidence grading for each critical question (see the Evidentiary Table in the original guideline document), the subcommittee drafted the recommendations and the supporting text synthesizing the evidence using the following guidelines:

Level A recommendations. Generally accepted principles for patient care that reï¬,ect a high degree of clinical certainty (e.g., based on evidence from 1 or more Class of Evidence I or multiple Class of Evidence II studies).

Level B recommendations. Recommendations for patient care that may identify a particular strategy or range of strategies that reï¬,ect moderate clinical certainty (e.g., based on evidence from 1 or more Class of Evidence II studies or strong consensus of Class of Evidence III studies).

Level C recommendations. Recommendations for patient care that are based on evidence from Class of Evidence III studies or, in the absence of any adequate published literature, based on expert consensus. In instances in which consensus recommendations are made, "consensus" is placed in parentheses at the end of the recommendation.

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and publication bias, among others, might lead to such a downgrading of recommendations.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Review comments were received from emergency physicians, cardiologists, individual members of the American College of Cardiology Foundation/American Heart Association, a patient representative, and members of American College of Emergency Physicians' (ACEP's) Medical-Legal Committee. Comments were received during a 60-day open-comment period, with notices of the comment period sent in an email to ACEP members, published in *EM Today*, and posted on the ACEP Web site. The responses were used to further refine and enhance this clinical policy; however, responses do not imply endorsement.

This clinical policy was approved by the ACEP Board of Directors on June 28, 2017.

This guideline was endorsed by the Emergency Nurses Association on August 22, 2017.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Recommendations for question 1 were based on 6 Class III studies. Recommendations for question 2 were based on 1 Class II and 1 Class III studies. Recommendations for questions 3 were based on 1 Class III study.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- The use of fibrinolytics when door-to-balloon (D2B) time is delayed may result in better long-term outcomes with a decrease in major adverse cardiac events (MACE).
- Patients who receive timely percutaneous coronary intervention (PCI) may experience better outcomes with a decrease in MACE.
- Opioids offer relief to chest pain patients by reducing discomfort and helping them relax during a highly stressful medical event.

Potential Harms

- Time estimates are challenging to obtain in the context of an emergency, therefore patients may not receive the recommended therapy within the appropriate time frame necessary to achieve optimal outcomes.
- Patients may decompensate en route to the percutaneous coronary intervention (PCI) facility resulting in poor outcomes.
- Opioids can potentially result in less salvageable myocardium if administered to patients having a myocardial infarction (MI).

Qualifying Statements

Qualifying Statements

- Policy statements and clinical policies are the official policies of the American College of Emergency Physicians (ACEP) and, as such, are not subject to the same peer review process as articles appearing in the journal. Policy statements and clinical policies of ACEP do not necessarily reflect the policies and beliefs of *Annals of Emergency Medicine* and its editors.
- This policy is not intended to be a complete manual on the evaluation and management of patients with ST-segment elevation myocardial infarction (STEMI) but rather a focused examination of critical issues that have particular relevance to the current practice of emergency medicine.
- It is the goal of the Clinical Policies Committee to provide an evidence-based recommendation when the medical literature provides enough quality information to answer a critical question. When the medical literature does not contain adequate empirical data to answer a critical question, the members of the Clinical Policies Committee believe that it is equally important to alert emergency physicians to this fact.
- This clinical policy is not intended to represent a legal standard of care for emergency physicians.
 Recommendations offered in this policy are not intended to represent the only diagnostic or management options available to the emergency physician. ACEP recognizes the importance of the individual physician's judgment and patient preferences. This guideline provides clinical strategies for which medical literature exists to answer the critical questions addressed in this policy.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Promes SB, Glauser JM, Smith MD, Torbati SS, Brown MD, American College of Emergency Physicians. Clinical policy: emergency department management of patients needing reperfusion therapy for acute ST-segment elevation myocardial infarction. Ann Emerg Med. 2017 Nov;70(5):724-39. [28 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Nov

Guideline Developer(s)

American College of Emergency Physicians - Medical Specialty Society

Source(s) of Funding

The American College of Emergency Physicians was the funding source for this clinical policy.

Guideline Committee

American College of Emergency Physicians (ACEP) Clinical Policies Subcommittee (Writing Committee) on Reperfusion Therapy for Acute ST-Segment Elevation Myocardial Infarction

Composition of Group That Authored the Guideline

Members of the Subcommittee (Writing Committee) on Reperfusion Therapy for Acute ST-Segment Elevation Myocardial Infarction: Susan B. Promes, MD, MBA (Subcommittee Chair); Jonathan M. Glauser, MD, MBA; Michael D. Smith, MD, MBA; Sam S. Torbati, MD; Michael D. Brown, MD, MSc (Committee Chair)

Members of the Clinical Policies Committee (Oversight Committee): Michael D. Brown, MD, MSc (Chair 2014-2017); Richard Byyny, MD, MSc (Methodologist); Deborah B. Diercks, MD, MSc; Seth R. Gemme, MD; Charles J. Gerardo, MD, MHS; Steven A. Godwin, MD; Sigrid A. Hahn, MD, MPH; Benjamin W. Hatten, MD, MPH; Jason S. Haukoos, MD, MSc (Methodologist); Graham S. Ingalsbe, MD (EMRA Representative 2015-2017); Amy Kaji, MD, MPH, PhD (Methodologist); Heemun Kwok, MD, MS (Methodologist); Bruce M. Lo, MD, MBA, RDMS; Sharon E. Mace, MD; Devorah J. Nazarian, MD; Jean A. Proehl, RN, MN, CEN, CPEN (ENA Representative 2015-2017); Susan B. Promes, MD, MBA; Kaushal H. Shah, MD; Richard D. Shih, MD; Scott M. Silvers, MD; Michael D. Smith, MD, MBA; Molly E. W. Thiessen, MD; Christian A. Tomaszewski, MD, MS, MBA; Jonathan H. Valente, MD; Stephen P. Wall, MD, MSc, MAEd (Methodologist); Stephen J. Wolf, MD; Stephen V. Cantrill, MD (Liaison with Quality and Patient Safety Committee); Jon Mark Hirshon, MD, MPH, PhD (Board Liaison 2016-2017); Rhonda R. Whitson, RHIA, Staff Liaison, Clinical Policies Committee and Subcommittee Revising the Reperfusion Therapy for Acute Myocardial Infarction Clinical Policy; Travis Schulz, MLS, AHIP, Staff Liaison, Clinical Policies Committee

Financial Disclosures/Conflicts of Interest

Relevant industry relationships: There were no relevant industry relationships disclosed by the subcommittee members for this topic.

Relevant industry relationships are those relationships with companies associated with products or services that significantly impact the specific aspect of disease addressed in the critical question.

Guideline Endorser(s)

Emergency Nurses Association - Professional Association

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Fesmire FM, Brady WJ, Hahn S, Decker WW, Diercks DB, Ghaemmaghami CA, Nazarian D, Jagoda AS, American College of Emergency Physicians Clinical Policies Subcommittee. Clinical policy: indications for reperfusion therapy in emergency department patients with suspected acute myocardial infarction. Ann Emerg Med. 2006 Oct;48(4):358-83. [86 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

| Guideline | Avail | ability |
|-----------|-------|---------|
|-----------|-------|---------|

| Available from the | American (| College of E | Emergency | Physician | s (ACEP) V | Veb site | | | | |
|--------------------|-------------|--------------|-----------|------------|------------|-----------|--------|--------|------|-----|
| A summary of this | guideline d | ptimized f | or mobile | viewing is | available | under the | CQ tab | at the | ACEP | Web |
| site | | | | | | | | | | |

Availability of Companion Documents

The following are available:

| American College of Emergency Physicians clinical policy development. Irving (TX): American College |
|---|
| of Emergency Physicians (ACEP). 3 p. Available from the American College of Emergency Physicians |
| (ACEP) Web site |
| ACEP clinical policy development process. Flow chart. Irving (TX): American College of Emergency |
| Physicians (ACEP). 1 p. Available from the ACEP Web site |

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on November 29, 2006. The information was verified by the guideline developer on March 12, 2007. The summary was updated by ECRI Institute on January 29, 2018. The updated information was verified by the guideline developer on March 5, 2018.

This NEATS assessment was completed by ECRI Institute on February 1, 2018. The information was verified by the guideline developer on March 5, 2018.

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| (ACEP) Web site | | | | | |

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